IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Allergan, Inc.,
Allergan Pharmaceuticals Ireland
Unlimited Company, and Allergan USA, Inc.,

Plaintiffs,

v.

Revance Therapeutics, Inc. and Ajinomoto
Althea, Inc. d/b/a Ajinomoto Bio-Pharma Services,

Defendants.

PUBLIC VERSION

C.A. No. 21-1411-RGA-LDH

[redacted]

COMBINED BRIEFING ON ALLERGAN'S
MOTION *IN LIMINE* NO. 1

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CERTIFICATE OF SERVICE

I hereby certify that on November 8, 2024, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on November 8, 2024, upon the following in the manner indicated:

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ALLERGAN'S MOTION *IN LIMINE* NO. 1

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FOR THE DISTRICT OF DELAWARE

Allergan, Inc., Allergan Pharmaceuticals Ireland Unlimited Company, and Allergan USA, Inc., Plaintiffs, v. Revance Therapeutics, Inc. and Ajinomoto Althea, Inc. d/b/a Ajinomoto Bio-Pharma Services, Defendants.	C.A. No. 21-1411-RGA-LDH [redacted]

ALLERGAN'S MOTION *IN LIMINE* NO. 1
TO PRECLUDE UNDISCLOSED EXPERT TESTIMONY

Allergan moves to preclude Revance's experts, Drs. Raj Suryanarayanan and Michael Meagher, from offering opinions at trial that were not disclosed in their expert reports, as required by Rule 26, and instead first raised at deposition. (*See, e.g.*, Ex. 1; Ex. 2.) The untimely disclosure of these new opinions was not justified or harmless under *Pennypack*.[1]

Dr. Raj Suryanarayanan's Undisclosed [redacted] and "Injectable" Opinions

Dr. Suryanarayanan should be precluded from testifying about previously undisclosed [redacted] and "injectable" theories. While Dr. Suryanarayanan represented that all of his opinions in this case are contained in his two expert reports (*see, e.g.*, Ex. 3 at 13:2-17, 14:20-23), he attempted to go beyond them during his deposition. *First*, Dr. Suryanarayanan's reports did not respond to Paragraph 147 of the rebuttal report of Allergan's expert, Dr. Christian Schöneich. (*See, e.g.*, *id.* at 140:10-16 ("**Q.** Look at paragraph 147, please. Can you confirm for me that your reports do not set forth a response to this paragraph of Dr. Schöneich's report? **A.** I do not recall addressing this in my report.").) In paragraph 147, Dr. Schöneich explained [redacted] (Ex. 4 ¶ 147.) Despite never responding to that opinion in his reports, Dr. Suryanarayanan attempted to inject new, unsolicited testimony at deposition that the [redacted] (Ex. 3 at 136:24-137:24 ("**A.** I don't recall talking about that in my report.").)

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[1] *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 904-05 (3d Cir. 1977). These factors include: (1) prejudice or harm to the party against whom the evidence is offered; (2) potential to cure the prejudice; (3) potential disruption of an orderly and efficient trial; (4) presence of bad faith or willfulness in failing to disclose the evidence; and (5) the importance of the information withheld. *Id.*

Second, Dr. Suryanarayanan offered a new opinion at deposition that certain formulation components in an alleged prior art reference ("Hunt 598") may not be "suitable for use in [an] injectable formulation," as contemplated by the asserted claims. (*See, e.g.*, *id.* at 55:10-57:25.) But this opinion was also not disclosed in either of his expert reports. (*See, e.g.*, *id.* at 57:12-25, 60:23-61:16 ("**Q:** Have you offered any opinion in your two expert reports regarding what excipients are suitable or not suitable for injectable formulation? **A:** I don't recall doing that.").)

Dr. Michael Meagher's Undisclosed Noninfringement Opinions

Dr. Meagher, Revance's expert to rebut infringement of claim 8 of the '748 patent, should be precluded from providing testimony at trial about the alleged level of residual nucleic acids present in Daxxify's drug substance based solely on documents and theories that he shoehorned into his deposition testimony. At deposition, Dr. Meagher testified that he did not intend to respond to any other infringement opinions "outside of what's described in [his] report." (Ex. 5 at 58:3-8; *see also* Ex. 6 § VII.A.) And in that report, Dr. Meagher's noninfringement opinions were limited to opining that Dr. Chamow, Allergan's infringement testing expert, had failed to account for the alleged impact one step in Revance's manufacturing process would have on quantifying nucleic acid levels in that drug substance. (Ex. 6 § VII.A.)

Nonetheless, later in his deposition, Dr. Meagher repeatedly sought to inject his newly minted (and incorrect) opinion regarding a Revance regulatory document, arguing that it contained data allegedly showing that Daxxify's drug substance contains residual nucleic levels above the range claimed in the '748 patent. (Ex. 5 at 115:24-116:22.) But this same document had been cited in the December 2023 opening report on infringement by Allergan's expert, Dr. Frank Gessler, and Dr. Meagher did not mention it anywhere in his noninfringement rebuttal report when he had the chance. (*Id.* at 298:4-299:2.) Likewise, Dr. Meagher provided new,

unsolicited testimony about documents cited in Dr. Chamow's opening report (*e.g.*, certificates of analysis) in an attempt to shoehorn his new opinion into the case. (*Id.* at 108:25-109:3.) Similarly, Dr. Meagher attempted to force in new noninfringement opinions about the impact of RNA on the evaluation of residual nucleic acid levels, while in the same breath claiming that a discussion of RNA did not appear in his reports because he simply "forgot to consider it." (*Id.* at 130:8-131:10.)

Drs. Suryanarayanan's and Meagher's Undisclosed Opinions Should Be Precluded

Pennypack Factors 1-4: Dr. Suryanarayanan's undisclosed opinions should have been provided in his reply report, where he had the last word on Revance's invalidity defenses. Likewise, Dr. Meagher's undisclosed opinions should have been provided in his rebuttal report, particularly since the documents upon which he relied were cited in the corresponding opening reports. (*See* Ex. 5 at 298:4-299:2; Ex. 7 ¶ 46; Ex. 8 ¶ 330.) Instead, Revance's experts waited until deposition to spring their new opinions through unsolicited testimony, which not only prejudices Allergan, but suggests a lack of good faith on behalf of Revance (who could have at least provided notice of these new opinions in advance of expert depositions). At that point, Allergan's experts had been deprived of the opportunity to properly consider these new opinions, and Allergan was not in a position to fully cross-examine Drs. Suryanarayanan and Meagher on them at the same moment they were presented. This significant prejudice cannot be cured given the imminence of trial in early December.

Pennypack Factor 5: Dr. Suryanarayanan provided nearly 500 pages of reports regarding the alleged invalidity of the Formulation Patents. Likewise, Dr. Meagher provided his noninfringement opinions in more than 11 pages of his 51-page rebuttal report. If these new arguments were important, Revance would have timely raised them in its voluminous reports.

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Dated: October 18, 2024

REVANCE'S OPPOSITION TO ALLERGAN'S MOTION *IN LIMINE* NO. 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Allergan, Inc., Allergan Pharmaceuticals Ireland Unlimited Company, and Allergan USA, Inc., Plaintiffs/Counterclaim Defendants, v. Revance Therapeutics, Inc. and Ajinomoto Althea, Inc. d/b/a Ajinomoto Bio-Pharma Services, Defendants/Counterclaim Plaintiffs.	C.A. No. 21-1411-RGA-LDH [redacted]

REVANCE'S OPPOSITION TO ALLERGAN'S MOTION *IN LIMINE* NO. 1 TO PRECLUDE UNDISCLOSED EXPERT TESTIMONY

Allergan's MIL 1 seeks exclusion of certain expert opinions of Drs. Suryanarayanan and Meagher that it elicited during their depositions at which Allergan had a full opportunity to explore the substance of their opinions. Allergan's MIL 1 at 1. The Court should deny the motion and not preclude the opinions at issue because (1) the disclosure of these opinions was timely and appropriate, so there is no need to impose a remedy; and (2) the *Pennypack* factors disfavor exclusion. Moreover, Allergan will have a full and fair opportunity to cross-examine these experts on their opinions at trial.

I. Drs. Suryanarayanan's and Meagher's Opinions Were Timely Disclosed.

Allergan's factual underpinning for MIL 1 is wrong. *First,* Allergan asks that Dr. Suryanarayanan be precluded from testifying about [redacted] because he supposedly failed to respond in his reply report to an opinion (appearing in a single paragraph) of an Allergan expert report. MIL at 1. That is not correct. Dr. Suryanarayanan countered Dr. Schöneich's [redacted] claims in ¶ 147 of his report by opining that [redacted] (Ex. A at ¶¶ 76-78, 204), in support of his overall conclusion that "Dr. Schöneich has not established conception of the Asserted Composition Claims." *See id.* at ¶¶ 73-75. Nor is it true that the testimony Allergan complains about was "unsolicited." Allergan's MIL 1 at 1. Rather, Allergan itself solicited this information by asking Dr. Suryanarayanan for [redacted] *See* Ex. B at 122:19-124:4. In response, Dr. Suryanarayanan (rightly) provided such a reason. *Id.*

Second, Allergan claims that Dr. Suryanarayanan offered "a new opinion at deposition that certain formulation components in an alleged prior art reference ('Hunt 598') may not be 'suitable for use in [an] injectable formulation.'" Allergan's MIL 1 at 2. But Dr. Suryanarayanan

opined in his report about the suitability of the formulations disclosed in Hunt. *See* Ex. C at ¶¶ 90-95, 271-274, 474-79, 692-96. At deposition, Allergan's counsel explored the bounds of Dr. Suryanarayanan's opinions by asking the witness about the suitability of certain polysaccharide-containing formulations in Hunt. *See* Ex. B at 60:8-61:6. Having explicitly sought clarification of Dr. Suryanarayanan's opinion on polysaccharide-containing formulations in Hunt, Allergan cannot now prevent Dr. Suryanarayanan from providing that same clarification at trial.

Finally, Allergan asks that Dr. Meagher be precluded from testifying about the level of residual nucleic acids in DAXXIFY®'s drug substance that is reflected in Meagher Ex. 28, a portion of Revance's BLA for DAXXIFY®. Allergan's MIL 1 at 2. Allergan mistakenly argues that because (1) Meagher Ex. 28 was cited in ¶ 330 of the opening report of Allergan's expert, Dr. Frank Gessler, and (2) Dr. Meagher responded to certain of Dr. Gessler's opinions in his rebuttal report, then Dr. Meagher should have addressed the document in that report. *Id.* But Dr. Meagher was not asked to address ¶ 330 of Dr. Gessler's report. *See* Ex. D at ¶¶ 2-3. The first time Meagher Ex. 28 was used in opinions relevant to Dr. Meagher was in Dr. Gessler's reply report, which Dr. Meagher reviewed in advance of his deposition. *See* Ex. E at 297:14-298:3.

Allergan again mischaracterizes Dr. Meagher's deposition testimony regarding Meagher Ex. 28 as "new [and] unsolicited." Allergan's MIL 1 at 1-3. To the contrary, Dr. Meagher responded to a direct and simple question at his deposition. *See* Ex. E at 115:19-116:22. Allergan makes similar arguments regarding documents cited in the opening report of Allergan's expert, Dr. Chamow and Dr. Meagher's testimony regarding residual RNA. Allergan's MIL 1 at 3. However, as with Meagher Ex. 28, Dr. Meagher's testimony on these documents was elicited by questions from Allergan's counsel. *See, e.g.,* Ex. E at 106:20-110:4, 129:19-131:16.

In sum, all of these opinions were properly and timely disclosed in response to Allergan's

own questions. That Allergan does not like Drs. Suryanarayanan and Meagher's answers should not preclude them from offering this testimony at trial. Revance should not be penalized for a calculated risk that Allergan chose to take at the experts' depositions.

II. The *Pennypack* Factors Disfavor Exclusion.

Because the opinions were properly disclosed, the *Pennypack* factors do not apply. If they did, then even the *Pennypack* factors weigh against exclusion.

Any claims of prejudice or bad faith are unfounded. *See* Allergan's MIL 1 at 3. The testimony at issue was elicited through questioning by Allergan. And Allergan should not now be heard to claim prejudice from testimony it sought, to which Revance's experts earnestly provided their opinions. Moreover, if Allergan truly believed it was prejudiced by Drs. Suryanarayanan's and Meagher's testimony, it should have raised its concerns with the Court at an earlier time when corrective action could have been taken, rather than on the eve of trial. *See Acceleration Bay, LLC v. Amazon Web Services, Inc.,* C.A. No. 22-904-RGA-SRF, 2024 WL 4164876, at *8, n.8 (D. Del. Sept. 12, 2024) (declining to preclude reliance on late-produced document because "Plaintiff effectively seeks discovery sanctions at the summary judgment phase" and "Plaintiff could have, and should have" raised the issue sooner); *see also nCube Corp. v. SeaChange Intern., Inc.*, 809 F. Supp. 2d 337, 347 (D. Del. 2011) (notice for beyond the scope objections informed by expert's "report and elaborations made" at deposition).

Allergan dismisses the importance of Drs. Suryanarayanan's and Meagher's testimony. If the testimony Allergan complains about is excluded, their ability to properly answer questions will be greatly diminished. Having had a full opportunity to explore the substance of their opinions at their depositions, the proper course for Allergan is to cross-examine Drs. Suryanarayanan and Meagher at trial. Its MIL 1 should be denied.

Dated: October 31, 2024

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ALLERGAN'S REPLY IN SUPPORT OF MOTION *IN LIMINE* NO. 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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ALLERGAN'S REPLY IN SUPPORT OF MOTION *IN LIMINE* NO. 1
TO PRECLUDE UNDISCLOSED EXPERT TESTIMONY

Dr. Suryanarayanan [redacted] Allergan did not "solicit" this opinion. The deposition questioning Revance cites (Ex. 1 at 120:10-124:4) involved whether [redacted], as required by the '625 patent. Rather than address that issue, Dr. Suryanarayanan offered an unrelated opinion focused on whether [redacted] This testimony is relevant, however, only to the '878 patent, which ***does not recite a buffer***. Revance's cited report paragraphs do not relate to the '625 patent, nor do they disclose a [redacted] opinion, as Dr. Suryanarayanan admitted (*see, e.g., id*. at 137:15-24, 140:10-16).

Dr. Suryanarayanan ("Injectable"): Revance focuses on opinions concerning the ***suitability*** of certain formulation excipients, but that is not what Allergan seeks to preclude. Allergan seeks to preclude opinions about the ***unsuitability*** of other formulation excipients, which Dr. Suryanarayanan never discussed in his reports. (*Id.* at 57:12-25, 60:23-61:16.)

Dr. Meagher: Revance cannot identify the opinions Allergan seeks to preclude ***anywhere*** in Dr. Meagher's two reports. Perhaps for this reason, Dr. Meagher attempted to railroad these opinions into his deposition when responding to questions about what ***was*** included in his reports. But Dr. Meagher had the chance to raise these opinions in response to Allergan's first-round reports, and his squandered opportunity should not be given new life now.

Allergan's Motion Is Appropriate:[1] This Court has excluded *in limine* expert opinions injected during deposition. *TQ Delta LLC v. Adtran, Inc.*, No. 14-954-RGA (D. Del. Aug. 17, 2020) (Ex. 2 at 4-5) (disagreeing "anything said in a deposition becomes a disclosed opinion").

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[1] Revance's cited cases are inapposite. For example, expert report scope was not addressed in *Acceleration Bay, LLC v. Amazon Web Services, Inc.*, 2024 WL 4164876, at *8 n.8 (D. Del. Sept. 12, 2024). And in *nCube Corp. v. SeaChange International, Inc.*, the substance of the allowed opinions were found to have been disclosed in the expert's report. 809 F. Supp. 2d 337, 347-50 (D. Del. 2011).

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Dated: November 7, 2024